

## REMARKS

### Rejection of claims 1 and 3-5 under 35 U.S.C. §102(b) as being anticipated by Kousai (US Pat. No. 4,874,374)

Examiner rejected claims 1 and 3-5 as being anticipated by Kousai. The rejection is respectfully traversed. Kousai discloses a medical tool introduction cannula and method of manufacturing the same. Kousai's medical instrument introduction cannula is useful as a guide means for introducing and indwelling a rod-like medical instrument such as a catheter and a guide wire "or the like in a blood vessel", see Abstract and col. 1, ln. 14 of ' 374. Kousai's cannula has a "distal end portion [that] is tapered thinner to be in tight contact with an inner cannula", See ' 374 col. 4, lns. 32-33, which pierces blood vessels.

The presently claimed invention is distinguishable from Kousai by the preamble. Unlike Kousai, the presently claimed invention is a breast implant injector device, which as the preamble connotes, is designed to guide a breast implant into the body cavity. The presence of "breast implant" in the preamble not only gives meaning to the claimed elements, but it is essential in pointing out that the device is to be used for breast implants. According to MPEP 2111.02, "the preamble is not given the effect of a limitation unless it breathes life and meaning into the claim, the preamble must be "essential to point out the invention defined by the claim." See MPEP 2111.02, citing *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951)."

The preamble clearly requires that the claimed element, "a hollow cylinder", be dimensioned and configured to receive a breast implant. Kousai's cannula is specifically tailored to articles having a particular size and designed appropriately for insertion in a blood vessel, see Fig. 8 and col. 5, ln. 55-62. Clearly, Kousai's cannula cannot receive a breast implant and is incapable of functioning as a breast implant introducer as claimed. Thus the present invention is distinguishable from and is not anticipated by Kousai.

Accordingly, Kousai does not disclose each and every limitation of the present claims and thus the 35 U.S.C. §102(b) anticipation rejection is improper. It is respectfully requested that the rejection of claims 1 and 3-5 be withdrawn.

Rejection under 35 U.S.C. §102(b) of claims 6 and 7 as being anticipated by Ash et al. (US Pat. No. 4,408,902)

Examiner found Ash to teach a combination of a breast implant injector device and an unfilled breast implant, defined as the end of (22) located in the musculature side of the dacron cuff (24; Fig. 6) and shown to be positioned in the interior of a hollow cylinder (10) during injection (Fig. 5). This rejection is respectfully traversed.

Ash discloses a slotted catheter emplacement guide, “which simplifies emplacement of a peritoneal catheter and also permits insertion through a very small abdominal opening.” See Abstract of Ash. The device of Ash is a catheter introducer guide useful for peritoneal dialysis. The slotted catheter of Ash is a “long ... [and] generally ‘cylindrical’” device, see ‘902 col. 2 lns. 62-64, having a uniform width from one end to an opposite end and being “approximately 12 inches by ¼ inches”, see ‘902 col. 2, lns.62-63. Ash fails to anticipate the present claims.

The present invention is specifically directed to a breast implant injector device and an unfilled breast implant, as stated in the preamble. The preamble of the presently claimed invention distinguishes the present invention from Ash. The presence of “unfilled breast implant” and “breast implant injector device” in the preamble breathes life and meaning into the claimed elements and ensures the device is used for breast implants. The claimed terms “breast implant” gives meaning to the claimed element “a hollow cylinder” in that the cylinder must be dimensioned and configured to receive the specific size of a breast implant.

Ash’s device places cuffed access devices into the body, see ‘902 col. 2, lns. 14-15. The guide of Ash is ¼ inch in diameter, col. 1 ln. 63. Unfilled breast implants have a diameter that is obviously larger diameter than the ¼ inch of the guide of Ash. The invention of Ash is clearly unsuited and incapable for use with breast implants.

Accordingly, Ash fails to anticipate the present application. It is respectfully requested that the present rejection be withdrawn.

35 U.S.C. §103(a) rejection of claims 8-11 over the combination of Ash et al. Kousai et al.

Examiner combines Ash and Kousai to show obviousness of the presently claimed invention, however in light of the arguments made above, the reference

patents fail to show the invention as claimed. The present rejection is respectfully traversed.

The preamble of the presently claimed invention is specifically directed to a breast implant injector device and an unfilled breast implant, as stated in the preamble. The preamble distinguishes the present invention from the reference patents, as both prior art references introduce grossly small objects into the body. Ash is directed to introducing a ¼ inch peritoneal catheter in the abdomen, and Kousai is directed to introducing rod-like medical instruments or the like in a blood vessel.

The presence of “unfilled breast implant” and “breast implant injector device” in the preamble breathes life and meaning into the claimed elements and ensures the device is used for breast implants. The words “breast implant” gives meaning to the claimed element “a hollow cylinder” in that the cylinder must be dimensioned and configured to receive the specific size of a breast implant. Neither of the applied references are capable of or suggest a breast implant introducer. Accordingly, the combination of Ash with Kousai fails to render the presently claimed invention obvious. It is respectfully requested that the present rejection be withdrawn.

35 U.S.C. §103(a) rejection of claim 12 over Ash et al. in view of Roser (US Pat. No. 6,102,896)

Examiner found Ash disclosed the invention as claimed except for enclosing the breast implant and cylinder in a sanitary package, which is taught by Roser. This rejection is presently traversed.

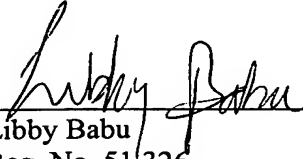
Roser discloses a disposable injector device. Roser is designed as single-use injector devices for injecting medicaments into the body. Specifically, Roser discloses a disposable injector device having snaps or tabs, wherein hand force is used to break the snaps or tabs and release a plunger and medicaments through the skin surface and into the body of the patient. See abstract of Roser. Roser’s device does not suggest a breast implant introducer and is incapable of introducing breast implants into the body. Even if Roser mentions sanitary packaging, Roser fails to make up for the deficiencies of Ash.

Accordingly, the combination of Roser with Ash fails to render the present invention obvious. It is respectfully requested that the present rejection be withdrawn.

The Examiner's indication of allowable subject matter is noted with appreciation. Applicants are grateful for the allowance of claim 13. For at least these reasons, Applicant respectfully submits that independent amended Claim 1 and claims 3-13 are in condition for allowance. If such is not the case, the Examiner is requested to kindly contact the undersigned in an effort to satisfactorily conclude the prosecution of this application.

Respectfully submitted,

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